

October 29, 1979

The press reports of the "PI/EK1 recommendation" by the RAC have really brought out the hate mail. <sup>1</sup> The correspondence includes Simring, Hartzman, Bereano (even Goldstein and two other members of the RAC), plus Solomon Garb, most of the letters contain the predictable reflexes. <sup>2</sup> This has been a difficult issue, however, because it was decided by a divided vote of the RAC. After the RAC acted, on September 7, I waited for the documents from Gartland. When we met in the last week in September, I was put out to find that Dr. Elizabeth Milewski, a new ORDA staff member, had prepared an extensive analysis of her own views of why the RAC minority was right. I thought this proper, but not before I received a full analysis of the decision and its background myself. ORDA must prepare these analyses of both sides before it begins any advocacy campaigns of its own. In the bluntest of terms, I "ordered " Gartland to prepare a full decision document in one week, and put the responsibility for its

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<sup>1</sup> Press reports attached here include:

- a) Article in Nature, Vol. 281, 9/13/79, p. 90. entitled "U.S. Expected to Exempt Most rDNA Experiments From Federal Regulation";
- b) Article in Nature, Vol. 282, 11/1/79, p.3. entitled "NIH Director Unlikely to Grant Exemption From Controls of DNA Experiments";
- c) Article (unidentified source) entitled, "Infection Risk Small in Some DNA Experiments".

<sup>2</sup> Copies of correspondence attached here include:

- a) Letter of 11/21/79 from Bereano to Harris;
- b) Letter of 12/29/79 from Goldstein to DSF;
- c) Letter of 12/30/79 from Wright to Harris;
- d) Letter of 1/21/80 from Simring to Harris;

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arrival ultimately upon Bernie Talbot. A 312 page document, plus the crude transcript of the RAC discussions, arrived on my desk on time. I also requested the actual tapes, but did not listen to them. I had heard the pre-vote discussion on a visit to the RAC on September 7, but from the privacy of the audio room. Thus I knew that enmities described later, in the letters of complaint, were not there at the actual moment of decision.

So we scheduled a full meeting of the "kitchen RAC" for mid-October. I scheduled Elizabeth W. and Sue Gottesman, who was in the minority on the vote, to first present the views of the minority for 20 minutes. As I questioned Sue, it was brought out that her major concern, and the only main one, related to Jonathan King's "auto-immune disease" anxiety. I questioned Emmett Barkley closely, and his statement that for E. coli, P1 had all the essential physical containment that one could get, P2 over P3 not adding any safety in handling enteric pathogens. Barkley's view seemed to startle Sue and most of the opposition faded quietly. (Fortunately, I'd decided in December to prohibit mouth pipetting in P1, a move essential to protecting against contamination in dealing with enteric pathogens).

Then 20 minutes were for Wally Rowe to give the majority view, on the P1/EK1 exemption with Maxine Singer, Mal Martin, Talbot, Zimmerman and Perpich, and with Nalton and Barkley listening critically.

By 4:00, I'd decided how this dilemma might be resolved.

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There would be no "exemption", (from the needed scaleup regulation, etc.). Instead, I would simply order that all work with EK<sub>1</sub> had to be in P1, with no national registration needed. For experiments where there might be protein expression, a little tougher treatment at the local level would be required. Above all, we'd also whip up a national "hype" on P1. This would include a letter from me to the president of all grantee institutions, enclosing a nice, bright, black and orange P1 sticker that they could put on their doors. This would put the leadership of the institutions on notice that they were responsible for enforcing the Guidelines.

Everyone took the order calmly. Talbot started to work. We've now been 10 days at it and are into the 3rd draft of the order . I also went to Secretary Harris to warn her of some possible moderate flack on this decision, but urged her not to draw the erroneous assumption that she's got to take any official action. In this era of new guidelines, the decision is delegated to me. (cf. decision document).